regulatory strategies to prevent children from initiating tobacco use and becoming addicted to nicotine, including restrictions on access and advertising, are likely to result in a significant reduction in tobacco-related illness and death. The information that has developed since 1980 that nicotine addiction is a pediatric disease thus provides a rationale for regulating tobacco in a manner that is likely to produce significant public health gains.

D. RESPONSE TO COMMENTS

Most of the comments that the Agency received generally recognized that an agency may change its position under appropriate circumstances. The comments differed widely, however, on whether such circumstances are present in this proceeding.

1. Some tobacco industry comments assert that relevant circumstances are unchanged since 1980—the date of the *ASH* decision and the last time the Agency evaluated this issue—and that therefore the Agency cannot offer a reasoned explanation for its change in position. Other comments differ sharply and contend that the available data have grown substantially. One comment stated that FDA has "obtained and considered substantial, new relevant data never previously considered, analyzed, or known by the FDA, never previously presented to or considered by Congress, and apparently, intentionally withheld by the tobacco industry from the FDA, Congress, and the American public."[1218] The Agency agrees that the evidence available to FDA today is far greater than the data available in 1980.

Of the comments contending that there has been no change in the legally relevant facts since 1980, one comment asserts that, because it has been widely reported for

[1218] Coalition on Smoking or Health, Comment (Jan. 2, 1996), at 6. *See* AR (Vol. 533 Ref. 102).

centuries that nicotine has "drug effects," there cannot be any new information on nicotine's drug effects that would warrant a change in the Agency's jurisdiction. This contention is unpersuasive. Although the Agency recognizes that nicotine has long been known to have some "drug effects," as set forth in this section and in section II. above, both the scientific understanding of nicotine's effects and the nature of the effects that are known to occur have changed dramatically since the last time that FDA considered its jurisdiction over tobacco products. The fact that nicotine is now universally recognized as highly addictive, but was generally unrecognized as such before 1980, adequately demonstrates the change in evidence on the nature of nicotine's drug effects. In addition, there has been a dramatic change in the evidence of consumers' use of tobacco products primarily for their pharmacological effects and on the tobacco industry's knowledge of nicotine's pharmacological effects and deliberate manipulation of nicotine levels. The new evidence on these issues fully warrants a change in position.

Tobacco industry comments further assert that tobacco industry research or studies comparable to such research were available in published scientific literature before 1980. The Agency notes that none of the evidence of tobacco industry research on nicotine was presented to the Agency in support of the ASH petitions. The fact that a few pieces of this evidence existed in 1980 but were never collected in one place or brought to the Agency's attention, moreover, is clearly not equivalent to the overwhelming accumulation of newer evidence before the Agency today, especially when coupled with the recent virtual consensus reached by the scientific community regarding the addictive nature of nicotine.

Similarly, some comments assert that, because ASH alleged in 1977 that nicotine was addictive and that many consumers used cigarettes to satisfy addiction, there has been no change to justify a new policy. ASH's allegations, however, did not constitute evidence. FDA must make its decisions on the basis of well-founded scientific facts. Today there is a well-founded consensus that nicotine is addictive in a huge proportion of its consumers. Neither the consensus nor the data to support it existed when FDA responded to the ASH petitions.

2. Comments both in favor of and opposed to the Agency's changed position discuss the current applicability of *Federal Trade Commission v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd mem.*, 203 F.2d 955 (2d Cir. 1953). One comment explained that the *Liggett & Myers* decision underscores the dramatic change in the quality and quantity of the evidence over the decades. The Agency agrees with that comment. The *Liggett & Myers* court, whose decision predated the 1964 Surgeon General's Report, found that the "soothing" properties of cigarettes were insufficient to establish that cigarettes were intended to affect the structure or function of the body. *Id.* at 576-577 ("[M]any things soothe the troubled mind of modern man and I do not feel that this is the type of effect which the statute contemplates."). No evidence was presented to the court to show that any "soothing" effects of cigarettes were due to nicotine or were even pharmacological in nature. FDA's current initiative is not based on unspecified "soothing" properties of cigarettes, but on the significant pharmacological effects of the drug nicotine, including its addictive effects, consumer use of tobacco for these effects, and on the tobacco industry's knowledge of nicotine's effects and its deliberate manipulation of nicotine delivery.

3. One public interest group comment asserts that there need not be any change in the underlying evidence for FDA to revise its application of the Act; disagreement with the prior policy alone is sufficient. The Agency agrees that the case law supports this proposition. *See, e.g., Rust*, 500 U.S. at 187; *Chevron*, 467 U.S. at 865. The Agency's change in position is fully justified, however, by the overwhelming new evidence that has become available to FDA since 1980. The Agency also notes that a change in the case law can justify a change in position and that new case law on "intended use" since 1980 provide further support for the Agency's determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

4. One comment argues that public attention on the health consequences of tobacco has changed its focus over the decades from tar content to nicotine addiction. That is, until the mid-1980's, public perception of the dangers of cigarette smoking was on tar and the components of tar rather than on the addictiveness of nicotine. The Agency finds that this historical point further supports the Agency's changed position regarding its jurisdiction over tobacco products without claims.

5. One comment states that new disclosures since the issuance of the Jurisdictional Analysis provide further support for FDA's assertion of jurisdiction. The Agency agrees that the evidence demonstrating that manufacturers of tobacco products intend to affect the structure and function of the body has continued to accumulate.

In sum, after review of all of the comments, the Agency finds that a change in FDA's position on jurisdiction over cigarettes and smokeless tobacco is warranted by the new evidence.

V. CONGRESS HAS NOT PRECLUDED OR PREEMPTED FDA FROM REGULATING CIGARETTES AND SMOKELESS TOBACCO

The comments of the tobacco industry and others assert that Congress has precluded or preempted the Agency from regulating cigarettes and smokeless tobacco. As described in this section, the Agency disagrees. Contrary to the position of the tobacco industry, Congress has neither expressly nor impliedly preempted or precluded FDA from regulating tobacco products. The language of the Federal Food, Drug, and Cosmetic Act (the Act) does not preclude FDA jurisdiction. Indeed, the history of FDA's regulation of tobacco shows that Congress understood that FDA could regulate tobacco products when an intent to affect the structure or function of the body is established. Moreover, FDA's assertion of jurisdiction is fully consistent with the narrowly crafted preemption provisions in the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act and with the existence of other statutes that address tobacco products.

A. THE PLAIN LANGUAGE OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DOES NOT PRECLUDE FDA JURISDICTION OVER TOBACCO PRODUCTS

"[T]he first place where we must look to see if Congress has spoken to the issue with which we are concerned and whether congressional intent in that regard is clear is the face of the statute." *Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995); *see also Time Warner Cable v. Doyle*, 66 F.3d 867, 875 (7th Cir. 1995), *cert. denied*, 116 S. Ct. 974 (1996). In the instant case, the express language of the Act does not exclude tobacco products from FDA's jurisdiction. The key language that defines drugs and devices as products "intended to affect the structure or any function of the body" nowhere excludes

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tobacco products. Because Congress has not excluded tobacco products from the drug and device definitions under the Act, it cannot be said to be clear that Congress intended to preclude FDA from regulating cigarettes and smokeless tobacco. *See Central Bank of Denver v. First Interstate Bank of Denver*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).

Congress is able to exclude and has excluded specific products, including tobacco products, from a statute's reach when it wishes to do so. For example, Congress has expressly excluded other products from FDA's jurisdiction under the Act. *See, e.g.*, 21 U.S.C. 321(i) (excluding "soap" from definition of "cosmetic"); 21 U.S.C. 392 (excluding meat products to the extent that they are covered by the Meat Products Inspection Act); 21 U.S.C. 321(s) (excluding pesticides from the definition of food additive under certain circumstances). Moreover, Congress has expressly excluded tobacco products from the reach of other regulatory statutes. *See* 15 U.S.C. 2052(a)(1)(B) (excluding "tobacco and tobacco products" from the definition of "consumer products" in the Consumer Product Safety Act); 15 U.S.C. 1261(f)(2) (excluding "tobacco and tobacco products" from the definition of "hazardous substance" in the Federal Hazardous Substances Act); 15 U.S.C. 2602(2)(B)(iii) (excluding "tobacco or any tobacco product" from the definition of "chemical substance" in the Toxic Substances Control Act); 21 U.S.C. 802(6) (excluding "tobacco" from the definition of "controlled substance" in the Controlled Substances Act); 15 U.S.C. 1459(a)(1) (excluding "tobacco or tobacco product" from the definition of "consumer commodity" in the Fair Packaging and Labeling Act). Indeed, tobacco is excluded from the definition of "dietary supplement" under the Act, but no similar exclusion appears in the definition of "drug" or "device." *See* 21 U.S.C. 321(g), (h), (ff).

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Accordingly, the absence of an express exclusion from the Act for tobacco demonstrates that Congress has chosen not to exclude from FDA's jurisdiction tobacco products that fall within the Act's definitions of "drug" or "device." Because Congress chose not to exclude tobacco products from the reach of the Act, the Agency need not read an exemption into the Act administratively.

B. THE LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DEMONSTRATES THAT FDA'S JURISDICTION OVER TOBACCO PRODUCTS IS NOT PREEMPTED OR PRECLUDED

Several comments from the tobacco industry and others assert that FDA lacks jurisdiction over cigarettes and smokeless tobacco without therapeutic claims because FDA communicated its prior position to Congress and Congress "acquiesced" in that interpretation by failing to enact legislation expressly authorizing FDA to regulate tobacco without therapeutic claims. These comments cite to unenacted legislation that, if passed, would have explicitly granted jurisdiction over tobacco products to FDA, and they contend that Congress' failure to enact these bills demonstrates that Congress concluded that FDA should not have jurisdiction over cigarettes. These comments variously rely on *Flood v. Kuhn,* 407 U.S. 258 (1972), *Zemel v. Rusk,* 381 U.S. 1, 11 (1965), *United States v. Rutherford,* 442 U.S. 544 (1979), *NLRB v. Bell Aerospace Co.,* 416 U.S. 267, 274-275 (1974), *United States v. Leslie Salt Co.,* 350 U.S. 383, 396-397 (1956), and *Ruhe v. Bergland,* 683 F.2d 102, 104 (4th Cir. 1982).

FDA disagrees with these comments on three independent grounds. Congress' failure to enact legislation explicitly granting FDA authority over tobacco products does not preclude FDA's assertion of jurisdiction over tobacco products because: (1) Congress

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has long known that FDA asserts jurisdiction over tobacco products that are intended to affect the structure or function of the body and has taken no action to alter this interpretation of FDA's jurisdiction; (2) even if Congress has acquiesced in an interpretation that FDA lacks jurisdiction, the Supreme Court has made clear that congressional acquiescence in an Agency's interpretation cannot be used to prevent the Agency from changing that interpretation; and (3) the Supreme Court has rejected the argument that Congress' failure to adopt legislation or amendments to a statute can be used to interpret a law adopted by a prior Congress.

First, the Agency does not agree that Congress has ratified or otherwise acquiesced in an interpretation of the Act that precludes FDA regulation of cigarettes and smokeless tobacco that are intended to affect the structure or function of the body. As discussed in section IV., above, FDA has long exercised legal authority to regulate tobacco products when the evidence established that the products had intended uses that fell within the Act's definition of a "drug." *See, e.g., U.S. Department of Agriculture Service and Regulatory Announcements, No. 13 (1914);*[1219] *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease). Indeed, as the comments point out, FDA has repeatedly told Congress that a tobacco

[1219] The USDA citation appears in the Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. I. at 5. *See* AR (Vol. 535 Ref. 96).

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product that falls within the definition of a drug or device because it was promoted to treat disease or to affect the structure or function of the body would be within the Agency's jurisdiction. *See, e.g., Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong., 2d Sess. 239 (1972) (FDA Commissioner Charles C. Edwards testified that "cigarettes and other tobacco products would be drugs subject to the Federal Food, Drug, and Cosmetic Act if medical claims are made for the product . . . [or] if recommended for use in controlling appetite . . .").

Second, even if the Agency had consistently interpreted the Act to preclude FDA regulation of tobacco products even when they were intended to affect the structure or function of the body, the legislative history cited by the tobacco industry would not preclude FDA from changing its interpretation. Acquiescence in an agency interpretation can be used only to confirm that an agency is acting within its authority, not to prevent an agency from changing its interpretation. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 45 (1983) ("While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation . . . even an unequivocal congressional ratification . . . of [a prior regulatory standard] would not connote approval or disapproval of an agency's later decision to rescind the regulation") (internal citations omitted); *Massachusetts v. Secretary of Health and Human Services*, 899 F.2d 53, 61 (1st Cir. 1990) ("the ratification of one agency policy by Congress does not preclude a change in that policy"), *vacated on other grounds,* 500 U.S. 949 (1991).

Finally, it is well established that "subsequent legislative history" cannot be relied upon to interpret previous legislation. The principal evidence cited by the comments that

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Congress intended to preclude FDA jurisdiction over tobacco is unenacted legislation that, if passed, would have explicitly granted jurisdiction over tobacco products to FDA. The comments contend that Congress' failure to enact these bills demonstrates that Congress intended to exclude tobacco products from FDA's jurisdiction over drugs and devices.

FDA disagrees. Congress can implement policy in only one way: passage of a bill by the House and the Senate that is either signed by the President or approved by an overridden veto. *INS v. Chadha*, 462 U.S. 919, 954-955 (1983); *Central Bank*, 114 S. Ct. at 1453. Congress has not enacted any legislation, signed by the President or approved by an overridden veto, that excludes cigarettes and smokeless tobacco from the drug and device definitions. The comments' argument is inconsistent with *Chadha* because it would allow Congress to change the law (by inaction) without any role for the President.[1220]

The gravamen of the comments' argument is that Congress' failure to modify the "drug" and "device" definitions after their original passage can be used to discern congressional intent as to the scope of those definitions. This argument has been rejected by the courts. Courts have repeatedly rejected claims that the failure of Congress to adopt legislation or amendments to a statute can be used to interpret a law adopted by a prior Congress. As the Supreme Court has explained:

> We have stated . . . that failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute. Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the

[1220] In addition, under Supreme Court authority, Congress's explicit grant of jurisdiction to an agency does not necessarily indicate that the agency previously lacked jurisdiction. *United States v. New York Tel. Co.*, 434 U.S. 159, 177 n.25 (1977).